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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/591,704

09/06/2006

Anne-Marie Pontis

0624-1004

3045

466 7590 07/02/2008

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EXAMINER

CARPENTER, WILLIAM R

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

07/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/591,704 | Applicant(s) PONTIS, ANNE-MARIE | |
| | Examiner WILLIAM CARPENTER | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/06/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/591704, filed on 26 September 2006.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13-16, 19-22, and 24, are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,601,207 ("Paczonay").

As regards to Claim 13, 14, 15, Paczonay discloses an oral device for administering a substance, comprising an oral insert (14) intended to be kept in a continuous manner in the mouth of a user (Figure 1) and a transfer means (10 and 12 in combination) for delivering a fluid (Column 1, Lines 40-43). Paczonay discloses the device to have a shape such that it could be housed entirely in the lateral region of the oral cavity situated outside a maxilla and inside a cheek (Figure 2A). Paczonay discloses that the device is made of a deformable, resilient, flexible material (Figure 2B, Column 1, Lines 48-55). As such it is believed to be inherent that were the device placed in the lateral region of the user's oral cavity the interaction of the insert with the

walls of the lateral region would produce a conjugation of shapes cooperating with each other so as to exert a resistance to extraction, especially were the lateral region of the user's mouth was contracted and subject to usual suction forces associated with the device being used for its intended function of delivering fluids.

As regards to Claim 16, while Paczonay fails to explicitly disclose that the oral insert comprises at least one part which can decrease in volume under the pressure of the walls of the oral cavity due to the disclosed composition of the insert (i.e. a resilient, flexible, deformable material) it is believed to be inherent that when deformed by compressive forces as intended the oral insert will exhibit some decrease in overall volume.

As regards to Claim 19, Paczonay discloses that the oral insert comprises several orifices (40) between which there is distributed a flow of fluid transferred between the oral cavity and the inside of the oral insert.

As regards to Claim 20, Paczonay discloses that the oral insert includes a front surface (26) that includes a plurality of pores (40) through which the flow of delivered fluid flows in a distributed manner.

As regards to Claim 21, Paczonay discloses that the oral insert comprises a storage chamber (18) communicating with the oral cavity in order to deliver thereto at least one fluid.

As regards to Claim 22, Paczonay discloses that the oral insert enables the oral cavity to communicate with at least one conduit (12) outside the user and conveying at least one fluid administered in the oral cavity.

As regards to Claim 24, Paczonay discloses that the oral insert of Claim 13 should be kept in a user's mouth (Figure 1) in order to repeatedly administer a substance orally.

4. Claims 13 and 23, are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,993,413 ("Aaltonen").

As regards to Claim 13, Aaltonen discloses an oral device for administration of a substance (Abstract) comprising at least one oral insert (7) intended to be kept in a continuous manner in the mouth of a user (Figure 1) and comprising a transfer means (9) for delivering thereto at least one fluid. Aaltonen discloses the oral insert to have a shape such that it can be housed entirely in the lateral region of the oral cavity situated outside the maxilla and inside the cheek (Figure 1), the interaction of the insert with the walls of the lateral region producing a conjugation of shapes cooperating with each other so as to exert a resistance to extraction (Figures 1 and 2).

As regards to Claim 23, Aaltonen discloses that the transfer means may include a product initially in solid form (Column 5, Lines 14-27) and interacting with the parotid saliva (PS) inside the oral insert to produce a product having a sufficiently reduced viscosity to allow flow through at least one orifice (5) communicating with the oral cavity (Figure 2).

5. Claims 13, 17, and 18, are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,289,127 ("Nelson").

As regards to Claim 13, Nelson discloses an oral device for administering a substance (Abstract), comprising at least one oral insert (18) intended to be kept in a

continuous manner in the mouth of a user (Figure 1) and comprising a transfer means (12) for delivering thereto at least one fluid. Nelson discloses the oral insert to have a shape such that it can be housed entirely in the lateral region of the oral cavity situated between the maxilla and the cheek, whereby interaction of the insert with the walls of the lateral region produces a conjugation of shapes cooperating with each other so as to exert a resistance to extraction (Figure 1).

As regards to Claims 17 and 18, Nelson discloses that the oral insert is formed of a deformable material such that the device may be custom bent such that it conforms to the contours of the cheek and gum (Column 2, Lines 47-65) thereby producing a resistance to extraction forces in conjunction with suction forces present in the oral cavity due to the constriction of the cheek.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/
Examiner, Art Unit 3767
06/25/2008

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763